

April 20, 2000

**VETERINARY SERVICES MEMORANDUM NO. 800.98**

Subject: Advertising and Promotional Materials

To: Biologics Licensees, Permittees, and Applicants  
Directors, Center for Veterinary Biologics

**I. PURPOSE**

This memorandum provides guidance concerning advertising and claims which are made about licensed veterinary biological products which are regulated under the Virus-Serum-Toxin Act (21 USC 151, et seq.)

**II. BACKGROUND**

The regulations in 9 CFR 102.4(b)(3) specify that before the Animal and Plant Health Inspection Service (APHIS) may issue a U.S. Veterinary Biologics Establishment License, applicants must file written assurance with APHIS that the biological products which are licensed to be prepared in the establishment will not be advertised so as to mislead or deceive the purchasers, and that the packages or containers in which the biologics are to be marketed will not bear any statement, design, or device which is false or misleading in any particular. Similarly, an application for a permit to import veterinary biological products must contain information regarding all claims to be made on labels and advertising matter used in connection with or related to the biological product to be imported. Mounted copies of final container labels, carton labels, and enclosures to be used with the imported product must be submitted as provided in part 112 of the regulations.

The Center for Veterinary Biologics (CVB) does not routinely monitor advertising materials that appear in various trade and scientific journals to determine if they contain statements concerning the product that are false and misleading. However, all reports of alleged false or misleading advertising or claims submitted to CVB are reviewed. Advertising or claims that are found to be false or misleading in any particular will be brought to the attention of the licensee or permittee by written notification as outlined in Section IV of this document. More drastic action may be taken in cases where inappropriate advertising or claims may render a product dangerous or harmful to such an extent that immediate action is necessary.

### III. GUIDELINES

#### A. Advertising Based on Labeling Submitted to CVB

Advertising or claims that restate information on labeling reviewed and filed by CVB and which do not include artwork, pictures, or other designs which by implication expand or modify such information as to make it false or misleading are acceptable. Advertising or claims which mislead by misquoting APHIS requirements or encourage the user to disregard label directions and otherwise use or handle the product in a manner that is inconsistent with filed labeling is considered false and misleading.

#### B. Advertising the Results of Studies

Data which validates protection claims such as prevention of infection, prevention of disease(s), and aid in the prevention of disease(s) are the basis for issuing veterinary biological product licenses and permits. Advertising or claims that accurately report the results of these studies in a manner that is not false or misleading is acceptable.

#### C. Advertising Claims for Enhanced Performance

Although performance parameters such as rate of gain, increased feed efficiency, and increased milk production may be monitored and included with the data from the protection study, such (performance) data are not considered in the evaluation of the biological product. Therefore, advertising products in a manner which, by inferences such as “data on file with USDA”, implies that performance claims have been reviewed and endorsed by APHIS is considered false and misleading.

#### D. Advertising the Results of Articles Published in Journals

Advertising that reports the results or conclusions of the author(s) of studies published in referenced scientific literature is acceptable. However, presenting or interpreting such results or conclusions in a manner that suggests that the results or conclusions of the author have been reviewed and approved by APHIS when they have not been approved is considered false and misleading.

#### E. Advertising Comparisons with Competitive Products

In making decisions regarding licensure, APHIS does not make its determination based on data or conclusions that compare the protection provided by one product to that of another competitive product. In addition, protocols for comparative studies of competitive products or the results of such studies that have been published in trade or scientific journals are not relevant to granting a license. The resolution of advertising issues or claims involving comparisons among products should not be submitted to APHIS for arbitration.

#### IV. COMPLIANCE PROCEDURES

The regulations in 9 CFR 105.1 specify, in part, that APHIS may suspend or revoke an establishment license, product license, or permit that is being used to facilitate the labeling or advertising of a product so as to mislead the purchaser in any particular. APHIS may take such action if other initiatives designed to gain compliance fail. Other compliance initiatives may consist of the following:

##### A. Letters of Advice

The Center for Veterinary Biologics-Inspection Compliance (CVB-IC) may send a letter of advice specifying the claim, design, or device that is considered to be false or misleading. Licensees or permittees may be asked to respond to APHIS' findings by supplying information to support continued use of a claim, design, or device or by agreeing to take specific corrective action in regard to a claim, design, or device within a specified time frame.

##### B. Letters of Warning

CVB-IC may send a letter of warning when the licensee or permittee does not respond to the letter of advice. Letters of warning could cite failure to take the specified corrective action as evidence of willful violation. Such violation could subject the license to suspension or revocation in accordance with 9 CFR 105.1(b).

##### C. Prereview of Advertising

APHIS does not normally review each piece of proposed new advertising. Occasionally, however, APHIS may agree to review advertising copy prior to its publication if the licensee is uncertain of the acceptability of a specific claim, design, or device.

/s/ Chester A. Gipson for

Alfonso Torres  
Deputy Administrator  
Veterinary Services